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79990 7590 06/23/2011 C. R. Bard, Inc. Bard Peripheral Vascular, Inc. 1415 W. 3rd Street P.O. Box 1740 Tempe, AZ 85280-1740				
EXAMINER				
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/603,952
Filing Date: June 25, 2003
Appellant(s): HARRIS ET AL.

Todd W. Wight
For Appellant

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed May 16, 2011, appealing from the Office action mailed September 16, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-11, 14-22, and 27 are rejected and pending.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS.” New grounds of rejection (if any) are provided under the subheading “NEW GROUNDS OF REJECTION.”

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant’s brief.

(8) Evidence Relied Upon

5,156,619	EHRENFELD	10-1992
4,530,113	MATTERSON	7-1985
5,782,916	PINTAURO et al.	7-1998

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ehrenfeld, US 5,156,619, which discusses a prior art example including a generally uniform surface (column 1, line 65, to column 2, line 5) and a first nominal or minimal inner diameter (column 1, lines 51-57; Figures 1-3) that tapers to a smaller second nominal or minimal inner diameter (column 2, lines 17-20) adjacent the end formation **23** (column 2, lines 6-9). Regarding claim 2 and others, the crimps **16** impart convexity to portions of the “toe” region, and the generally circular cylindrical geometry of segment **12** (Figure 1) likewise defines a convexity. Regarding claim 7 and others, a second end formation would have been inherent from column 1, lines 5-8.

Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrenfeld, US 5,156,619. Regarding claim 6, diameters within the particular ranges would have been obvious from the ranges specified by Ehrenfeld (column 1, lines 54-57; column 4, lines 10-15) and from the diversity of blood vessel sizes known to the ordinary practitioner. Regarding claim 15 and others, PTFE would have been an obvious alternative thread or coating in view of column 1, lines 13-20.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson, US 4,530,113. Forming the shunt **10** of Figure 6 without the pleats or corrugations **12** (so as to create a *constant* inner dimension) would have been an obvious step backward (column 6, lines 49-59) in order to simplify manufacture. The inner arc lengths and diameters along the ends **44** are variable by virtue of the oblique cut (column 7, lines 9-11), which also defines an elongate, non-circular opening of greater area than that of a cross-section transverse to a central axis along an intermediate portion of the shunt **10**. Attention is also directed to column 6, line 32.

Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pintauro et al., US 5,782,916. Figure 13 illustrates an end formation **114** *capable* of connection to a blood vessel opening (column 3, lines 58-64; column 4, lines 35-43; column 9, line 8 et seq.) and a first diameter portion surrounding the valve **124** and tapering to a smaller second diameter portion (column 7, lines 66-67) adjacent the end formation **114**, which defines openings having non-circular perimeters (Figures 1, 8, 10, 14, and 15; column 8, lines 5 and 14-18; column 4, lines 8-20; etc.). Regarding claim 2, a second transverse diameter may be defined near the reinforcing ring **17** or **117** (Figures 1, 8, 10, and 13), and the *internal* toe surface

is concave (Figure 13). Regarding claim 21, the second engagement may be viewed as involving anchor **116**, with valve **124** defining a lesser third diameter portion.

Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pintauro et al., US 5,782,916. Regarding claim 6, the particular dimensions would have been within the realm of obvious variants in view of the diversity of pertinent anatomical dimensions found in the animal kingdom and in view of column 4, lines 17-20 and 32-34; column 8, lines 3-6 and 38-44; and column 8, line 49 et seq. Regarding claim 15 and others, PTFE would have been immediately obvious from column 8, lines 45-48.

(10) Response to Argument

Reference is made to pages 4 and 5 in the Office action of September 16, 2010, for a discussion of the applied patents. Regarding Ehrenfeld and the “taper[ing] to a smaller second diameter” (Appellant’s claim 1, lines 3-4), Appellant’s remarks completely overlook the passage relied upon by the examiner (Ehrenfeld: column 2, lines 17-20). Additionally, the wrong Ehrenfeld figures are reproduced on pages 11 and 12 of the Appeal Brief; the rejection is based on the prior art Figures 1-3 rather than on Ehrenfeld’s Figures 4 and 5. Moreover, the representations of Appellant’s own Figures 11 and 12 (Appeal Brief, pages 16 and 11, respectively) are inaccurate relative to those of the original disclosure (U.S. parent application serial no. 09/762,761; paper of October 5, 2001, entitled “Miscellaneous Incoming Letter” in the electronic file). This is particularly important with regard to the issue of how much Appellant’s so-called “first diameter portion” (e.g., claim 21, lines 3-4) actually varies along the length of the tube.

In regard to Ehrenfeld and instant claim 2, a “chamber” is defined as “a natural or artificial enclosed space or cavity” (*Merriam-Webster’s Collegiate Dictionary*, 10th ed.: 1996), and a “diameter” is “a chord passing through the center of a figure or body” (*ibid.*). It is the examiner’s position that there innately exists a line segment parallel to the straight portion **22** and passing through the center of the chamber space and another line segment transverse or perpendicular to said straight portion and passing through said center; the chamber longitudinal and transverse dimensions (as measured through said center) are the respective lengths of these line segments or chamber space diameters, with the geometric form (and boundary) of the chamber being defined in part by the cut **18** (Figure 1). The first or parallel diameter “corresponds” to a heel and a toe of the end formation in the sense that it generally extends from a heel region near crotch **15** to a toe region of the end formation **23**. Nowhere does Appellant’s claim 2 require the diameters to extend across the *opening* of the chamber. [It is noted that in column 2, lines 17 and 18, “crotch **16**” should instead read --crotch **15**--, as evidenced by column 1, line 64, and Figures 1 and 2 of Ehrenfeld.]

With regard to Appellant’s claim 3 and “a non-laminar nature with a shear stress inducing relationship to a wall of said blood vessel” (lines 2-3), *any* fluid flow through a lumen is inherently accompanied by shear stress at the luminal walls, and a non-laminar or turbulent component of flow is introduced by the confluence at the bifurcation formed by the graft or prosthesis. Attention is directed to Appellant’s own definition of “non-laminar” (page 3a, last paragraph, of the original specification in parent application serial no. 09/762,761). Regarding claim 7 and others, since a synthetic vascular graft typically has two ends, one of ordinary skill would have inferred “at least one end” (Ehrenfeld: column 1, line 7) to mean that two integral

flanges (one at either end) were contemplated by Ehrenfeld, and such a configuration certainly existed in the prior art at the time of the present invention, as evidenced by, for example, Figure 6 of the applied Matterson patent (further discussed below).

The alleged recitation of “the diameter extending along a majority of the length of the tube” (Appeal Brief: page 15, lines 9-10) is inaccurate relative to lines 2-3 of Appellant’s claim 18. Under the rules of English grammar, the language “extending along a majority of the length of the tube” modifies the immediately preceding term *portion* rather than diameter. The instant claims should be read in light of the original drawings and specification instead of the misleading diagram in the Appeal Brief at the top of page 16.

With regard to claim 27 and Matterson, Appellant argues that “[f]orming the shunt **10** of Figure 6 without the pleats or corrugations **12**” (Office action of September 16, 2010: page 3, line 6) “would render the Matterson graft inoperable for its intended purpose” (Appeal Brief: page 19, lines 1-3). The examiner disagrees, because blood pressure in an arterial bypass, for example, helps to maintain the graft in its open tubular configuration, and numerous materials and reinforced materials (e.g., 623/1.32-1.33 of the U.S. Patent Classification System) not requiring pleats or corrugations are (and were) used in this crowded art.

As for Pintauro et al., Appellant contends that “the rubber used for the Pintauro device would not facilitate suturing to a blood vessel” (Appeal Brief: page 21, lines 23-24), but the present claims are not directed to a surgical method and do not positively recite sutures as elements of the prosthesis. The Pintauro et al. device is certainly *capable* of being deployed in a surgical procedure, and even catheter delivery often entails surgical incisions through the skin and a blood vessel or other anatomical structure; moreover, biological adhesives and numerous

other attachment means may be used in lieu of sutures. Appellant further states that “[t]he addition of the valve within the fluid flow path to close the fluid flow for low pressure differentials would stop the flow of blood if used as a vascular prosthesis” (Appeal Brief: page 21, last three lines). But venous valves, for example, actually *assist* the flow of blood upwardly along the legs of a human (as seen from a cursory review of subclass 623/1.24 in the U.S. Patent Classification System). And the Pintauro et al. implant is *structurally capable* of being surgically installed in the circulatory system of a laboratory animal or cadaver if for no other reason than to test the Appellant’s hypotheses as to functionality.

Appellant discusses at length various geometrical issues, but since the claimed tubular axis may be curved (and is curved in the Applicant’s own embodiments) and since terms like “dimension” (e.g., Appellant’s claim 27, line 3) are quite broad, no further comment is deemed necessary. Attention is again directed to the grounds of rejection above and the remarks made on pages 4 and 5 in the final Office action of September 16, 2010.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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